UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

)	
AGA Medical Corp.,)	
)	
Plaintiff,)	No. 0:10-cv-03734-JNE-JSM
)	
V.)	
)	
W. L. Gore & Associates, Inc.,)	
)	
Defendant.)	
)	
)	

AGA MEDICAL CORPORATION'S MEMORANDUM OF LAW IN OPPOSITION TO W.L. GORE & ASSOCIATES, INC.'S MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Defendant W.L. Gore & Associates, Inc. ("Gore") has failed to show that there are no genuine issues of material fact and that it is entitled to summary judgment on the three issues raised in its motion. Summary judgment should be denied for the reasons set forth below.

I. GORE'S MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT SHOULD BE DENIED BECAUSE THE HELEX HAS STRUCTURE THAT IS EQUIVALENT TO A "CLAMP HAVING A THREADED BORE"

Gore tries to avoid trial on AGA's patent infringement claims by arguing for a legally incorrect infringement analysis of the claim term "means for securing said device to a delivery system." Federal Circuit case law makes clear, however, that Gore's argument is wrong as a matter of law. AGA's expert properly analyzed and applied the Court's claim construction of that term in his infringement analysis.

While never being explicit, Gore is essentially arguing that to prove that the HELEX device has structure that is the equivalent to a "clamp having a threaded bore" Dr. Bhattacharya must identify structure in the HELEX that is equivalent to the structure of the clamp that performs **the clamping function.** Gore is wrong as a matter of law.

The "clamp having a threaded bore" performs two discrete functions. One end of the device serves to clamp the wires of the embodiment depicted in the patent. The other end of the device has the "threaded bore," which serves to secure the device to the delivery catheter. The fact that the part performing these two functions is called a clamp has the pernicious effect, subtly capitalized on by Gore, of leading one to assume that

whatever else the clamp might do, it must **always** clamp; after all that is its name. But regardless of whether the part is called a fitting, a connector, or a clamp, the infringement analysis for this means-plus-function element is the same, and what is relevant for the means-plus-function analysis is only the underlying structure of the clamp that performs the claimed function.

Here the claimed function is "securing the device to a delivery system." That is **the only function claimed.** In considering whether the structure of the HELEX is an equivalent structure to the structure disclosed in the '738 patent, only that structural part of the "clamp having a threaded bore" that performs the claimed function of "securing the device to a delivery system" is considered. *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 145 F.3d 1303, 1308 (Fed Cir. 1998). The structural part of the clamp that performs the clamping function is not considered.

A. Gore Misstates the Legal Standard for Means Plus Function Limitations

Gore asserts that it is the court's job to determine whether the accused device performs the function recited in the claim and contains structure that is identical or equivalent to the corresponding structure disclosed in the specification. (Dkt. 367 at 4.) That is wrong. The determination of whether the accused device literally meets a meansplus-function limitation is a question of fact for the jury. *IMS Tech., Inc. v. Haas*Automation, Inc., 206 F.3d 1422, 1430 (Fed. Cir. 2000). Thus, if there is a genuine dispute regarding whether the accused device contains an identical or equivalent structure to the structure disclosed in the specification, summary judgment must be denied.

B. It is Reversible Error to Import an Unclaimed "Clamping" Function into the Court's Claim Construction of the "Means For Securing Said Device to a Delivery System" Limitation

The Federal Circuit has been consistent in holding that it is error to "import[] unclaimed functions when analyzing the way in which the disclosed embodiment [the corresponding structure] performed the claimed function" during an infringement analysis. *Applied Med. Res. Corp.*, v. U.S. Surgical Corp., 448 F.3d 1324, 1335 (Fed. Cir. 2006). The only structural aspect of the clamp that performs the recited function is the threaded bore, and, as mandated by *Applied Medical*, "the inquiry should be restricted to the way in which the structure performs the *properly-defined function* and should not be influenced by the manner in which the structure performs other, extraneous functions." *Id.* at 1334.

In *Chiuminatta*, 145 F.3d at 1308, the patented device was a rotary saw for sawing wet concrete. The claimed function at issue was "means . . . for supporting the surface of the concrete." The corresponding structure shown in the patent to perform the recited function was a "skid plate." The court said that the specification "clearly identifies the structure performing that [claimed] function as the skid plate...." *Id.* However, to decide infringement, the structural details of the skid plate were examined in greater detail to identify the specific structural aspects of the skid plate that performed the claimed function because there were other structural aspects on the skid plate that performed non-claimed functions. *Id.* The other structural aspects of the skid plate functioned "to reducing wobbling" and "support the weight of the saw." *Id.* The Federal Circuit said "[t]hese [other] structural aspects [of the skid plate] are thus not the means by which the

saw 'supports the surface of the concrete' and accordingly are not to be read as limiting the scope of the means clause." *Id.* at 1308.

The same holds true here. The function of clamping, and the structural aspects that do the clamping, cannot be considered during the infringement analysis. *See Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259, 1266–68 (Fed. Cir. 1999) (relying on *Chiuminatta* and rejecting consideration, for purposes of equivalence under 112 ¶ 6, of functions and structure that were unrelated to the specific function of the means-plusfunction recitation.) Rather, the proper infringement analysis involves an examination of only that part of the structure of the "clamp having a threaded bore" that is necessary to perform the claimed function of "securing the device to the delivery system." That is what Dr. Bhattacharya did. As explained below, that is also what Gore's own expert, Dr. Gorman, did.

C. AGA's Expert, Dr. Bhattacharya, Properly Analyzed and Applied the Court-Ordered Claim Construction of "Means for Securing Said Device to a Delivery System"

AGA's expert, Dr. Bhattacharya, testified that he applied the Court's construction for the claim term "means for said device to a delivery system."

- Q. And with respect to the claim term, "means for securing said device to a delivery system," did you apply the court's construction for both the claimed function and the corresponding structure for that term?
- A. Yes.

(Carpenter Decl. Ex. 1 at 108:25–109:5.) Dr. Bhattacharya also stated this in his expert report. (Bhattacharya Decl. Ex. 1 at ¶¶ 26–28 (providing Court's construction and stating that "[his] analysis is based on . . . the specific constructions adopted by the Court as provided above. ...").)²

As Gore acknowledges, Dr. Bhattacharya began his infringement analysis by identifying the "clamp having a threaded bore" as the overall structure for purposes of the analysis. (Bhattacharya Decl. Ex. 1 at ¶ 61; Dkt. 367 at 6–7.) He then discussed the part of that structure that performs the claimed function of "securing the device to the **delivery system.**" (Bhattacharya Decl. Ex. 1 at ¶¶ 61–63 (emphasis added).) It is under this **functional** analysis that Dr. Bhattacharya refers to the threaded bore (which is part of the overall "clamp" structure) because, as he opined, it is the threaded bore part of the clamp structure that **performs the function** of "securing the device to the delivery system."

Next, Dr. Bhattacharya clearly identifies the structure in the accused HELEX device (the distal eyelet) that is the **equivalent** of the "clamp having a threaded bore" for purposes of performing the claimed function of "securing the device to the delivery system." Dr. Bhattacharya's analysis spans seven pages and provides thorough factual

¹ All references to "Carpenter Decl.," unless otherwise noted, are to the Declaration of Jonathan D. Carpenter in Support of AGA Medical Corporation's Memorandum of Law in Opposition to W.L. Gore & Associates, Inc.'s Motion for Summary Judgment, and accompanying exhibits, filed herewith.

² All references to "Bhattacharya Decl.," unless otherwise noted, are to the Declaration of Dr. Kaushik Bhattacharya in Support of AGA Medical Corporation's Memorandum of Law in Opposition to W.L. Gore & Associates, Inc.'s Motion for Summary Judgment, and accompanying exhibit, filed herewith.

foundation for his conclusions and specific identification of the accused structure through figures and text; it is not limited to two paragraphs as Gore contends, nor is it an unsupported conclusion. (Bhattacharya Decl. Ex. 1 at ¶¶ 61–69; Dkt. 367 at 9.)

In addition to identifying the accused structure, Dr. Bhattacharya explained why one of skill in the art would view the HELEX's distal eyelet as equivalent to the structure of a "clamp having a threaded bore" for purposes of "securing the device to the delivery system." (Bhattacharya Decl. Ex. 1 at ¶¶ 61–69.); see Applied Med., 448 F.3d at 1335– 37 (concluding, contrary to the district court, that the expert's declaration provided a sufficient explanation to raise a material fact as to why one of skill in the art would view both structures as performing the claimed function in substantially the same way to achieve substantially the same result.) Dr. Bhattacharya also provided evidence of interchangeability between the structure in the accused device and the disclosed structure. See Al-Site Corp. v. VSI Int'l Inc., 174 F.3d 1308, 1316 (Fed. Cir. 1999) (providing that evidence of known interchangeability between structure in the accused device and the disclosed structure has also been considered an important factor). As such, Dr. Bhattacharya's opinion provides more than sufficient evidence of structural similarity to establish a genuine issue of material fact for the jury.

D. Gore's Expert, Dr. Gorman, Analyzed Equivalence of the "Means for Securing" Limitation in Exactly the Same Way

Dr. Gorman stated that "[a] clamp having a threaded bore is the only structure identified in the '738 patent for securing the devices described therein to the delivery system." (Carpenter Decl. Ex. 2 at 50.) Dr. Gorman also stated that "**the inventors only**

described a nut-and-bolt type of threaded connection as the means for securing their device to the delivery system." (*Id.* (emphasis added).) In describing how the claimed structure performs the function of securing the device to the delivery system, Dr. Gorman repeatedly referred only to the "threaded connection." (*Id.* at 51–53 ("[a]]ll threaded connections provide very strong attachment"; "[t]he inventors accomplished this goal by using a threaded connection"; "[a] threaded connection has been known for decades"; "a threaded connection solves that problem"; "[o]ne benefit of a threaded connection is that the amount of force for engagement and disengagement is relatively low"; "the threaded connection allows the operator to retract the device"; "[operator can redeploy the device] easily because of the strength of the threaded connection") (emphasis added).) At all times Dr. Gorman referred to the threaded bore part of the overall "clamp" structure. At no point, did he ever refer to or consider the clamp part of the overall "clamp" structure.

E. Summary

Based on the proper legal methodology for assessing the claimed "means for securing the device to said delivery system" and the evidence presented, a reasonable jury could find that the HELEX infringes. Gore's motion should be denied.

II. THE ASSERTED CLAIMS COMPLY WITH THE WRITTEN DESCRIPTION REQUIREMENT OF § 112(a)

Gore argues that, in order to satisfy the written description requirement, the specification of the '738 patent must demonstrate that the inventors invented a non-metal fabric device. That is not the law. Rather, the law merely requires that the specification

(including the claims as originally filed) allow persons skilled in the art to recognize that the inventor invented what is claimed. "What is claimed" in asserted claims 23 and 30 of the '738 patent is a septal occluder having a flexible, resilient central portion that allows two disks to move laterally with respect to one another. Claims 23 and 30 do not affirmatively claim a metal or non-metal fabric device; they are agnostic as to what material the occluder is made of. The invention—a flexible, resilient central portion that allows disk lateral movement—can be achieved regardless of the occluder material.

Claims are permitted to be, and usually are, broader than the specific preferred embodiment of the patent. In this case, claim 23 as issued in the '738 patent is essentially identical to claim 23 of the application as originally filed. The fact that the application was filed with claims that were agnostic as to the material that the device was made of is strong evidence that the inventors considered their invention to be not limited to the specific material used in the preferred embodiment. This is further confirmed by the specification's repeated description of metal fabric as merely being "preferred."

Prior to the filing of the '738 patent application, septal occluders were known to be made out of a wide variety of different materials, including metal fabric, cloth fabric, metal wires, polymeric foam, and elastomeric balloons. That being the case, it is not surprising that the inventors of the '738 patent would contemplate that their invention was not limited to the use of one specific material. What mattered to the inventors was that the device, whatever it was made of, have a flexible, resilient central portion that allows lateral movement of the disks. This is what claims 23 and 30 claim. Under these circumstances, Gore cannot satisfy its burden of proving by clear and convincing

evidence that claims 23 and 30 lack an adequate written description. The inventors were well within their rights to obtain claims that were not limited to metal fabric.

A. Legal Standard

1. Summary Judgment Standard and Gore's Burden

The '739 patent is presumed valid, and Gore must prove invalidity by clear and convincing evidence. *Enzo Biochem Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 962 (Fed. Cir. 2002). Whether a patent's claims are invalid under 35 U.S.C. § 112 is a question of fact. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). Thus, to prevail on summary judgment, Gore must show by clear and convincing evidence that there are no genuine issues of material fact and that a reasonable jury could not conclude that the written description requirement of § 112 has been satisfied.

2. The Written Description Requirement

A patent applicant is not required to describe in the specification every conceivable embodiment of his or her invention. *Cordis Corp. v. Medtronic Ave, Inc.*, 339 F.3d 1352, 1365 (Fed. Cir. 2003). Nor is an applicant required to describe features that are not critical parts of the claimed invention. *E.g. Cordis*, 339 F.3d at 1365. Rather, "the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*citing Vas-Cath*, 953 F.2d at 1563). The test "requires assessment from the viewpoint of one of skill in the art"—whether such a person would

recognize that the applicant invented what is claimed. *Pandrol USA*, *LP v. Airboss Ry*. *Prods.*, *Inc.*, 424 F.3d 1161, 1165 (Fed. Cir. 2005).

"[T]he level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Ariad*, 598 F.3d at 1351. Relevant factors include "the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, and the predictability of the aspect at issue." *Id*. (internal citation omitted).

B. The Asserted Claims Meet the Written Description Requirement

Misleadingly quoting *Ariad*, Gore argues that AGA must show that "the specification 'clearly allow[s] persons of ordinary skill in the art to recognize that the inventor invented [a non-metal fabric device]." (Dkt. 367 at 15 (brackets in original).)

The actual *Ariad* quote states that the description must "clearly allow persons of ordinary skill in the art to recognize that the inventor invented *what is claimed.*" *Ariad*, 598 F.3d at 1351 (emphasis added). "What is claimed" in asserted claims 23 and 30 is, inter alia, a medical device having "two enlarged diameter portions and a flexible central portion" that "allows lateral movement" of the disks with respect to one another. The material out of which the claimed device is made—whether metal fabric or non-metal fabric, both of which were well-known in the art—is simply not an element of this invention. Under the law, inventors are permitted to omit such elements from the claimed invention without violating the written description requirement.

1. AGA Was Permitted to Obtain Claims That Were Not Limited to the Metal Fabric Employed in the Preferred Embodiment

The Federal Circuit and its predecessor court have repeatedly held that claims can be written broadly to cover embodiments not disclosed in the specification without violating the written description requirement. For example, in *In re Rasmussen*, the court found no violation of the written description requirement when a patent applicant sought to add broader claim language "adheringly applying," even though the specification described only one method of applying adhesive. 650 F.2d 1212, 1215 (C.C.P.A. 1981). The court recognized: "that a claim may be broader than the specific embodiment disclosed in a specification is in itself of no moment." *Id*.³

Similarly, in *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 93 F.3d 1572 (Fed. Cir. 1996), the Federal Circuit considered the validity of a claim to a surgical stapler that did not specify where on the device a lockout mechanism was located. The Court criticized the district court for "confus[ing] a claim not supported by the specification, which is not allowable, with a broad claim, which is." *Ethicon*, 93 F.3d at 1582 n.7. The Court went on:

If Fox did not consider the precise location of the lockout to be an element of his invention, he was free to draft claim 24 broadly (within the limits imposed by the prior art) to exclude the lockout's exact location as a limitation of the claimed invention.... *Such a claim would not be*

³ This is also supported by the oft-cited canon of claim construction that it is improper to limit the scope of a claim to the specific embodiment disclosed in the specification. *E.g. Gemstar-TV Guide Int'l, Inc. v. ITC*, 383 F.3d 1352, 1366 (Fed. Cir. 2004). The fact that a canon of claim construction prohibits reading limitations from the preferred embodiment into the claims shows that there is nothing wrong with the claims being broader than the preferred embodiment.

unsupported by the specification even though it would be literally infringed by undisclosed embodiments.

Id. (emphasis added); see also Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., 670 F.3d 1171, 1188–89 (Fed. Cir. 2012) (specification's description of a prosthesis with wall thicknesses of 0.2 to 0.8 mm was sufficient to support claims that were not limited to a particular wall thickness, even though the specification also stated that "[g]rafts falling outside [the specified] ranges have been found to be marginal or clinically unacceptable"); Lampi Corp. v. Am. Power Prods., Inc., 228 F.3d 1365, 1377–78 (Fed. Cir. 2000) (specification's description of only identical half-shells was sufficient to support claims that covered non-identical half-shells); Utter v. Hiraga, 845 F.2d 993, 998 (Fed. Cir. 1988).

In the present case, the preferred embodiment of the occluder described in the '738 patent is made of metal fabric. However, the inventors did not consider the material that the occluder is made of to be critical to the invention of having a flexible, resilient central portion that allows the disks to move laterally relative to each other. That being the case, there was nothing improper about AGA obtaining claims (like asserted claims 23 and 30) that did not specify the preferred material. The asserted claims are no different than the hundreds of thousands of other patents whose claims are broader than the preferred embodiment and cover products not precisely disclosed by the specification.

2. The '738 Patent Describes Metal Fabric as a Preferred, Not a Necessary, Aspect of the Invention

Throughout the specification, the '738 patent repeatedly identifies the ability of the flexible, resilient central portion to allow the disks to move laterally as a key feature

that differentiates the occluder device from the prior art. (*See*, *e.g.* Carpenter Decl. Ex. 3, col.1, ll.6–13; col.1 l.64–col.2 l.4; col.2 ll.18–31; col.2 l.63–col.3 l.1; col.3 ll.43–44; col.3 l.61–col.4 l.15.)

The '738 patent does *not* describe the material from which the occluder is made as being a critical aspect of the invention. While the preferred embodiment shown and described in the patent is made out of metal fabric, the "Summary of the Invention" section expressly states that the device of the invention is only "*preferably* formed from a continuous tubular metal fabric." (*Id.*, col.3 ll.13–14 (emphasis added).) Other portions of the patent similarly refer to the use of metal fabric as merely "preferred":

- "The device is **preferably** made from a continuous tubular metal fabric . . . " (*Id.*, Abstract (emphasis added).)
- "The device of the present invention is **preferably formed** from a continuous tubular metal fabric" (*Id.*, col.3 ll.12–14 (emphasis added).)
- "In the **preferred embodiment**, the occluding device is formed from a single continuous tubular metal fabric." (*Id.*, col.5 ll.3–4 (emphasis added).)
- "The device is **preferably made** from a 0.005 inch nitinol wire mesh." (*Id.*, col.10 ll.57–59 (emphasis added).)

In fact, the '738 patent notes that metal fabric was well known in the art. (*Id.*, col.7 ll.41–44 ("A wide body of knowledge exists for forming nitinol in such devices, so there is no need to go into great detail here on the parameters of a heat treatment for the nitinol fabric preferred for use in the present invention.").)

3. The Original Claims Show the Inventors Contemplated Non-Metal Fabric Devices

The application that resulted in the '738 patent was filed on February 6, 1998 with 27 claims. (Carpenter Decl. Ex. 4 at AGA_GORE0017721–755.) Of the 27 claims as originally filed, seven did not contain a "metal fabric" limitation. (*Id.* at AGA_GORE0017739–42.) For example, independent claim 20, from which the presently-asserted claims depend, was for a "collapsible medical device, comprising two enlarged diameter portions and an elastic central portion interconnecting the two enlarged diameter portions" (*Id.* at AGA_GORE0017741.) Similarly, dependent claim 23 was for the elastic central portion of claim 20 "shaped to form a resilient portion to thereby pull the two enlarged diameter portions toward the other." (*Id.*) In fact, asserted claim 23 of the '738 patent as issued is essentially identical to claim 23 of the application as filed. (*Id.*)⁴ Gore has not alleged—and it is not the case—that AGA ever broadened claims during prosecution to remove a "metal fabric" limitation to ensnare a competitive product or for any other reason.

4. The '738 Patent Does Not Distinguish the Invention Over the Prior Art Based on the Use of Metal Fabric

The specification refers to prior art patents from King, Das, Sideris, and Marks. (Carpenter Decl. Ex. 3 at col.2 ll.5–11.) Those references disclose devices made of a wire frame supporting non-metal fabric disks (referred to as patches). The '738 patent

⁴ The only difference is that the word "elastic" was changed to "flexible" in claim 23 and in claim 20, from which claim 23 depends. (Carpenter Decl. Ex. 4 at AGA_GORE0017774.)

criticized the *configuration* of these prior art devices but not the materials they were made from, as Gore contends (Dkt. 367 at 17–18):

- "Patches that are attached to a common axis of the hub may become problematic when the septal defect to be occluded has eccentric openings. Since the patches are attached to a common rigid axis, at least one of the eccentric openings may not be completely covered by the respective patch." (Carpenter Decl. Ex. 3 at col.1 1.64–col.2 1.2.)
- "The rigid or semi-rigid hub prevents adjustment of the patches to compensate for the eccentric openings." (*Id.* at col.2 ll.2–4.)
- "[T]he size of the prior devices is inherently limited by the structure and form of the device. . . . Consequently, the prior devices require an oversized retention skirt positioned on each side of the defect." (*Id.* at col.2 11.32–33, 38–39.)
- "Also, these disclosed devices tend to be rather expensive and time-consuming to manufacture." (*Id.* at col.2 ll.43–44.)
- "Further, the shape of the prior devices (for example squares, triangles, pentagons, hexagons and octagons) require a larger surface contact area and have corners which may extend to the free wall of the atria." (*Id.* at col.2 ll.46–49.)
- "Furthermore, the previous devices require a [large diameter] introducing catheter, making it impossible to treat children affected with congenital defects with these devices." (*Id.* at col.2 ll.53–54.)

Moreover, during prosecution of the '738 patent, the patent office examiner initially rejected the claims as unpatentable over two references showing metal fabric. (Carpenter Decl. Ex. 4 at AGA_GORE0017766–768.) One of the cited references was AGA's own Patent No. 5,725,552 ("the '552 patent"). (*Id.*) And, in response to this rejection, AGA did not attempt to distinguish its invention based on the use of metal fabric. (*Id.* at AGA_GORE0017775–780.)

5. Gore Has Failed to Show That Either of the Two Circumstances
That Give Rise to a Meritorious Written Description Defense
Are Present in this Case

Because claims are permitted to be broader than the disclosed embodiment(s), it is not enough to establish invalidity for lack of written description to merely show that the claims read on embodiments not disclosed in the patent, as Gore contends. Rather, the cases that find invalidity for lack of written description invariably fall into one of two categories: (1) where the technology involved is sufficiently complex, undeveloped and unpredictable that disclosure of one or more embodiments does not reasonably show possession of a broadly claimed invention; and (2) where "the entirety of the specification clearly indicates that the invention is of a much narrower scope." *See Bilstad v. Wakalopulos*, 386 F.3d 1116, 1125-26 (Fed. Cir. 2004) (describing two "exceptions" to the general rule that disclosure of one species will support a generic claim); *see also Cooper Cameron Corp. v. Kvaerner Oil-Field Prods., Inc.*, 291 F.3d 1317, 1323 (Fed. Cir. 2002); *Cordis Corp.*, 339 F.3d at 1365.

In the present case, it is not clear whether Gore is arguing that this case falls within the first category or the second category, although its arguments appear to be more focused on the second. Nonetheless, AGA will address both.

a. Gore Has Not Presented Clear and Convincing Evidence That the Art is Sufficiently Complex, Undeveloped and Unpredictable to Render Invalid Claims That Do Not Require Metal Fabric

The first category of cases where lack of written description is found recognizes that in fields that are complex and unpredictable, for example the chemical or

biotechnical arts, those skilled in the art may not be able to predict the operability of undisclosed species. *Bilstad*, 386 F.3d at 1125 (discussing *In re Curtis*, 354 F.3d 1347 (Fed. Cir. 2004)). *Ariad* falls squarely within this category. *Ariad* concerned claims directed to methods of regulating cellular responses to external stimuli. 598 F.3d at 1340. The Federal Circuit noted that broad claims directed to a functional genus is a problem "that is particularly acute in the biological arts." *Id.* at 1352–53. In finding that the claims failed the written description requirement, the Federal Circuit explained that "the state of the art at the time of filing was primitive and uncertain, leaving Ariad with an insufficient supply of prior art knowledge with which to fill the gaping holes in its disclosure." *Id.* at 1358. The same is true of the other pharmaceutical and/or biotechnology-related cases that Gore string-cites. (Dkt. 367 at 14 n.5.)

The *LizardTech* case relied on by Gore also falls into this first category. *LizardTech* involved a complex and unpredictable technology known as discrete wavelet transforms ("DWTs") for data compression of digital images. *LizardTech*, *Inc. v. Earth Rcs. Mapping, Inc.*, 424 F.3d 1336, 1337 (Fed. Cir. 2005). The patent was directed to the creation of a "seamless" array of DWT coefficients so that multiple portions of the digital image could be broken apart into "tiles" without creating edge artifacts. *Id.* at 1339.

While the specification disclosed only one particular method for creating a seamless DWT, the patentee sought and obtained claims on any method of creating a seamless DWT. *Id.* at 1339–40. In this complex area of technology, it was undisputed that the disclosure of a single embodiment was not sufficient to enable one skilled in the art to

make the invention in any other way than in the specific way disclosed in the specification. *Id.* at 1345–46.

This first category of cases does not apply, however, where the technology is more simple and predictable, such as in the mechanical fields. *See Bilstad*, 386 F.3d at 1126 ("In the mechanical world—a fairly predictable field—it is wholly conceivable that manipulation in a small number of directions may convey to one skilled in the art that [the patentee] indeed described manipulation in a 'plurality' of directions."); *In re Curtis*, 354 F.3d at 1354–55 (discussing *In re Smythe*, 480 F.2d 1376, 1383 (C.C.P.A. 1973)). In such a case, those skilled in the art are likely to appreciate possession of a generic invention based on the disclosure of even a single embodiment. *See id*.

In the present case, Gore has not presented undisputed clear and convincing evidence establishing that the art of septal occluders at the time of the '738 patent was particularly complex, undeveloped or unpredictable. To the contrary, septal occluders are mechanical devices. At the time the '738 patent application was filed, various materials from which implantable devices could be made were known, as were their mechanical characteristics. The '738 patent itself notes that single nitinol wire (not woven) was known in the art. (Carpenter Decl. Ex. 3 at col. col.7 ll.36–42.) The '738 patent also refers to various prior art patents. They disclose septal occluders made of a wire frame combined with a non-metal fabric patch. (*Supra* Section II.B.5.) This is clear, uncontroverted evidence that materials other than metal fabric were well known in the art at the time the original application was filed. Gore makes much of the fact that the '738

patent criticizes these references. (*See* Dkt. 367 at 12.) But the patent criticizes the devices because of their *configuration*, not because they lacked metal fabric.

Further, as AGA's expert, Dr. Mullins, points out, "devices made out of a variety of materials other than metal fabric were conventional at the time of filing." (Mullins Decl.⁵ Ex. 1 at 118.) Dr. Mullins' testimony on this point is not "conclusory" (see Dkt. 367 at 11–12, 19); it is evidence that one of ordinary skill reading the original specification and claims would have "reasonably" understood that the invention was not limited to any one particular material. See Ariad, 598 F.3d at 1351. Dr. Mullins also corroborates his own experience with discussion of the devices disclosed in the King, Das, Sideris, and Marks references that are discussed in the '738 patent. (Mullins Decl. Ex. 1 at 120.) Nor can Dr. Mullins' opinion be contorted—as Gore attempts—into an "obviousness" opinion. (See Dkt. 367 at 21.) Dr. Mullins clearly opines that one of ordinary skill reading the original specification—such as himself—"would have appreciated that a claim not including a specific material limitation could be embodied by a device made out of any of [the] conventional materials." (Mullins Decl. Ex. 1 at 120.) That is all *Ariad* requires—that the original specification "reasonably conveys" to one of skill that the inventors possessed the claimed invention. Ariad, 598 F.3d at 1351.

In fact, Gore's own expert agrees with Dr. Mullins on this point. Dr. Gorman's report points out that at the time of filing, "people in the field were designing occlusion

⁵ All references to "Mullins Decl.," unless otherwise noted, are to the Declaration of Dr. Charles E. Mullins in Support of AGA Medical Corporation's Memorandum of Law in Opposition to W.L. Gore & Associates, Inc.'s Motion for Summary Judgment, and accompanying exhibits, filed herewith.

devices out of *various types and combinations of materials*, including balloons, *metal wire frames*, foams, and other types of polymeric materials." (Carpenter Decl. Ex. 5 at 218 (emphasis added).) AGA and Gore are in apparent agreement that, at the time of the invention, those skilled in the art had experience making occluders from a variety of known materials.

b. Contrary to Gore's Arguments, the Specification as Filed Does Not Indicate That Metal Fabric is a Critical Element of the Invention.

The second circumstance where claims are held invalid for lack of written description is when "the entirety of the specification clearly indicates that the invention is of a much narrower scope." Cooper, 291 F.3d at 1323. For this category of cases to apply, there must be no indication in the specification that the inventor contemplated a broader invention. For example, in the Gentry Gallery case relied on by Gore, the claims were directed to a sectional sofa having a console and recliner controls. *Gentry Gallery*, Inc. v. Berkline Corp., 134 F.3d 1473, 1475 (Fed. Cir. 1998). The original disclosure identified the console "as the only possible location for the controls." *Id.* at 1479. "[The] broadest original claim was directed to a sofa comprising, inter alia, 'control means located upon the center console." *Id.* Based on this initial disclosure and the inventor's admission at trial that "he did not consider placing the controls outside the console until he became aware that some of [plaintiff's] competitors were so locating the recliner controls," the Federal Circuit limited the claims to sofas having the recliner control located on the console. Id.

Importantly, the second category of cases universally involves the situation where the patentee had broadened the claims during prosecution by removing a limitation that was present in all the claims as originally filed. This includes all of the cases cited by Gore at pages 13–14 of its brief other than *Lizardtech*, discussed above. *See Gentry* Gallery, 134 F.3d at 1479; Tronzo v. Biomet, Inc., 156 F.3d 1154, 1159 (Fed. Cir. 1998) (claims broadened in CIP application to omit requirement that hip implants have a conically-shaped cup); Atl. Research Mktg. Sys., Inc. v. Troy, 659 F.3d 1345, 1355 (Fed. Cir. 2011) (claims added in reissue process to include "barrel nut-only attachment design" that was previously undisclosed and in fact characterized as a trade secret at time of original application); ICU Med., Inc. v. Alaris Med. Sys., 558 F.3d 1368, 1377 (Fed. Cir. 2009) (original claims required a "spike" structure, while "the asserted spikeless claims were . . . added years later during prosecution"); PowerOasis, Inc. v. T-Mobile USA, Inc., 522 F.3d 1299, 1308 (Fed. Cir. 2008) (original claims were significantly broadened by a subsequent continuation-in-part application); Maytag Corp. v. Electrolux Home Prods. Inc., 448 F. Supp. 2d 1034, 1066 (N.D. Iowa 2006) (patentee amended claims during prosecution to remove the teardrop-shaped groove limitation).

The reason for this is because the "specification" for the purpose of determining compliance with the written description requirement includes the claims as originally filed. *N. Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 938 (Fed. Cir. 1990). In fact, many cases find the written description requirement to be satisfied based on nothing more than the claims as originally filed. *See Crown Packaging Tech., Inc. v. Ball Metal Beverage Container Corp.*, 635 F.3d 1373, 1380–81 (Fed. Cir. 2011); *Union Oil Co. of*

Cal. v. Atl. Richfield Co., 208 F.3d 989, 998 n.4 (Fed. Cir. 2000); In re Koller, 613 F.2d 819, 823 (C.C.P.A. 1980) ("original claims constitute their own description"); In re Gardner, 480 F.2d 879, 880 (C.C.P.A. 1973). Because the claims as originally filed are part of the specification, a defendant cannot show that "the entirety of the specification clearly indicates that the invention is of a much narrower scope" unless the issued claims are broader than the claims as originally filed.

No such broadening occurred here. Seven of the original twenty-seven claims submitted with the '738 application as originally filed did not include a limitation directed to the material from which the device was formed. (*Supra* Section II.B.3.) This includes asserted claim 23, which is essentially identical to claim 23 of the application as filed. (*Id.*) The fact that the allegedly "critical" metal fabric limitation was *not* present in all of the claims as originally filed is very strong evidence that the inventors contemplated an invention that did not require that limitation. *In re DiLeone*, 436 F.2d 1404, 1405 (C.C.P.A. 1971) (finding generic claims supported by the specification in part because "the originally filed claims, which are part of the disclosure, recite [] 'a diamine' without further limitation as the first reactant."); *see also Crown Packaging*, 635 F.3d 1381 ("The added limitation [of the dependent claims] would not be needed if the inventors had in mind that in all cases driving would occur outside the reinforcing bead.").

Contrary to the assertion on page 10 of Gore's brief, *Ariad* did not change the law in this regard. *Ariad* merely clarified that original claims do not "automatically" satisfy the written description requirement. 598 F.3d at 1351. That is true because of cases, like

Ariad, that fall within the first category discussed above. When the technology at issue is highly complex and unpredictable, the fact that the originally-filed claims were broad may not be sufficient to show possession of that broadly-claimed subject matter. Absent a showing of complex, unpredictable technology, however, Gore has not cited a single case finding a lack of adequate written description that did not involve the situation where the patentee broadened the claims during prosecution relative to what was originally filed.

Moreover, nothing in the remainder of the '738 specification indicates that the particular material from which the claimed devices are constructed is a critical part of the invention. It does not distinguish prior art on the basis of metal fabric. Gore focuses only on the fact that the embodiment disclosed in the patent is constructed from a metal fabric. But when discussing the invention generally, the Summary of the Invention section of the patent does not limit the device to a particular material. (*See supra* Section II.B.2.) To the contrary, the specification, including the Summary of the Invention, clearly and repeatedly identifies the disclosed metal fabric device as merely being "preferred." (*Id.*) These facts are totally inconsistent with Gore's argument that the feature is critical to the invention. *See In re Robins*, 429 F.2d 452, 456 (C.C.P.A. 1970) (a rejection under § 112 ¶ 1 must fail when "the specification contains a statement of [the] invention which is as broad as [the] broadest claims").

Finally, the testimony of AGA's expert is further evidence that renders summary judgment in Gore's favor inappropriate. Dr. Mullins is an interventional cardiologist who

has implanted more than 450 septal occluders and has over 45 years of experience. He states as follows in his report:

The language in the specification as filed, including the language of the original claims, along with the fact that septal occlusion devices made out of a variety of materials other than metal fabric were conventional at the time of filing, would convince one of ordinary skill in the art that the inventors "possessed" the claimed subject matter

(Mullins Decl. Ex. 1 at 117–118.) This is testimony must be accepted as true and renders inappropriate Gore's request for summary judgment on the factual issue of adequacy of the written description.

C. Summary

The specification, including the claims, shows the inventors invented, at the time the application was filed, what is claimed—a septal occlude having a flexible, resilient central portion that allows the disks to move laterally with respect to each other.

III. CLAIMS 23 AND 30 ARE NOT ANTICIPATED BY THE '552 PATENT

Gore argues that the '552 patent anticipates the '738 patent, even though (a)

Gore's own expert has admitted that the '552 patent does not disclose the claimed

"flexible central portion that allows lateral movement of the disks with respect to each
other"; and (b) the U.S. Patent and Trademark Office distinguished and allowed the '738
patent in suit over the '552 patent specifically because it did not disclose this feature.

Gore improperly attempts to bootstrap the disclosure of the '738 patent into the '552
patent's disclosure through a mischaracterization of AGA's expert's testimony,
conclusory statements of Gore's expert, and an irrelevant comparison of unimportant
similarities between the '552 and '738 patents. No reasonable jury could find that Gore

has produced clear and convincing evidence establishing that the '552 patent teaches or inherently discloses a central portion that allows lateral movement of the disks.

A. Factual Background

When the application for the '552 patent was filed, Dr. Amplatz had not yet invented a way to occlude a long-tunnel, eccentric opening PFO by shaping the central portion of an occluder so that it allowed the disks to move laterally with respect to each other. At that time, people of ordinary skill in the art had not even recognized that there was a need to deal with long-tunnel, eccentric opening PFOs. (Carpenter Decl. Ex. 6 at 178:12–181:14.) As Dr. Gorman conceded, it would be very unusual to need lateral movement of the disks to close an atrial septal defect (Carpenter Decl. Ex. 7 at 124:12–18; 126:8–11), and therefore there was nothing in the '552 patent that even hinted at the invention of the '738 patent.

Indeed, when the Patent Office examined the application for the '738 patent it determined that the '552 patent did not anticipate or render obvious the claims of the '738 patent. (Carpenter Decl. Ex. 4 at AGA_GORE0017777–782.)

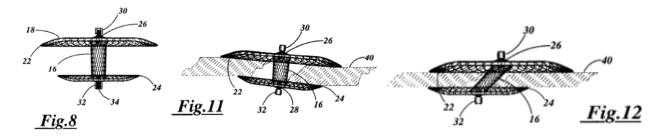
AGA's expert, Dr. Mullins, testified that the '552 patent does not teach a central portion that allows lateral movement. (Carpenter Decl. Ex. 6 at 173–209.) Furthermore, as explained in AGA's brief accompanying its summary judgment motion, Gore's expert, Dr. Gorman, admitted that the '552 patent did not teach, disclose, or even suggest that it was desirable to have a flexible central portion that allows lateral movement of the disks with respect to each other. (Dkt. 350 at 9 and 12.)

B. Figure 17 of the '552 Patent Does Not Inherently Have a Central Portion that Allows Lateral Movement

Gore argues that the '552 patent inherently anticipates the '738 patent, reasoning that Dr. Mullins testified that Figure 17 of the '552 patent is the same as Figure 8 of the '738 patent and that the specifications of the two patents demonstrate that they are the same device. Dr. Mullins did not so testify, and the patent specifications suggest no such thing.

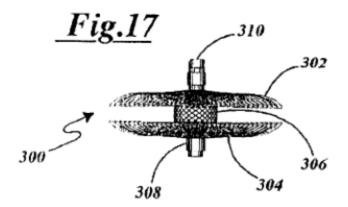
1. Dr. Mullins Did Not Testify that Figure 17 of the '552 Patent and Figure 8 of the '738 Patent Show the Same Embodiment

The '738 patent depicts a number of different occluder configurations having a flexible central portion to facilitate the closing of a PFO. One such configuration is illustrated by Figures 8, 11 and 12:



Figures 8, 11 and 12 all depict the same device. (Carpenter Decl. Ex. 3 (Figure 8 is "partially stretched along its longitudinal axis" (col.4, ll.40–41); "FIG. 11 is a . . . view of the embodiment of FIG. 8 . . ." (col.4 ll.49–50); "FIG. 12 is a . . . view of the embodiment of FIG. 8 . . ." (col.4, ll.52–53)).)

Figure 17 of '552 patent, in contrast, depicts a representation of an occluder having a wide waist sized large enough to fill an atrial septal defect:



Dr. Mullins' unwavering deposition testimony was that the '552 patent did not disclose an occluder with a central portion that allowed lateral movement of the two disks. (Carpenter Decl. Ex. 6 at 165:24–166:12; 173:9–174:5; 178:12–179:18; 182:22–25.) Therefore, Gore asked Dr. Mullins whether he had an opinion about what it would take to make changes in the drawing designated Figure 17 in the '552 patent to arrive at the drawings designated Figures 8, 11, and 12 of the '738 patent. (*See* Carpenter Decl. Ex. 6 at 210:22–214:23.) This is the pertinent questioning:

- Q. ... I just need to know that you don't have opinions sitting here today of what it would take for a person of ordinary skill in the art to get from Figure 17 of the Kotula '552 patent to Figure 11 of the '738 patent?
- A. I didn't consider it.

(*Id.* at 213:9–14.)

During Dr. Mullins' deposition, Gore's attorney asked Dr. Mullins to confirm that he "also didn't consider what it would take to get from" Figure 17 of the '552 patent to Figure 8 of the '738 patent.

Q. Okay. And sitting here today, as a person of ordinary skill in the art, you did—you also didn't consider what it would take to get from

Figure 17 in the Kotula '552 patent to Figure 8 in the Kotula '552—in the '738 patent?

(*Id.* at 213:15–19.) Dr. Mullins answered:

A. Same figure, essentially. No. (*Id.* at 213:20.)

Gore now represents the above testimony as an admission by Dr. Mullins that Figure 17 in the '552 patent and Figure 8 in the '738 patent are the same figure. (Dkt. 367 at 24–25.) That is not, however, what Dr. Mullins said. The context of Mullins' testimony shows that Dr. Mullins was saying that, because **Figure 11 and Figure 8 of the '738 patent are the same Figure**, he did not have an opinion about what it would take to get to Figure 8, just as he did not have an opinion on what it would take to get to Figure 11.

Because Figures 11 and 8 of the '738 patent are unequivocally the same figure, it would make sense for Dr. Mullins to say in response to Gore's deposition questions that those figures are the same. It would not make sense, however, for Dr. Mullins to say that Figure 17 of the '552 patent was the same figure as Figure 8 of the '738 patent. That would have been a reversal of his unequivocal testimony that the '552 patent did not disclose the invention of the '738 patent. Furthermore, the "no" in his answer is inconsistent with Gore's position. If Dr. Mullins intended to say that Figure 17 of the '552 patent was the same as Figure 8 of the '738 patent, he would have said "yes" he had an opinion because it would take nothing to go from Figure 17 to Figure 8; they are the same. Gore has misrepresented Dr. Mullins' testimony to the Court.

Everyone at the deposition understood that Dr. Mullins was saying that it was Figures 11 and 8 from the '738 patent that are the same figure. Mr. Zayed made a comment right after Dr. Mullins' answer showing that is how he interpreted Dr. Mullins' testimony and to explain to Gore's counsel that the question concerning Figure 8 was wasting Dr. Mullins' time because it was the exact same question that Gore's counsel posed with respect to Figure 11 which the '738 patent clearly identified as the same device. He said:

MR. ZAYED: Well, the patent says that Figure 11 is Figure 8, the '738 patent. So – the '738 patent specifically references Figure 11 as being Figure 8.

(*Id.* at 213:22–25.)

Then, Gore's attorney turned to Figure 12 of the '738 patent. She asked:

Q: Dr. Mullins, did you ever consider what it would take to get from the Figure 17 in the ... '552 patent to Figure 12 in the '738 patent?

A: No, it's the same—same argument.

(*Id.* at 214:17–21.) Dr. Mullins' answer that he didn't have an opinion for Figure 12 either, and that it was the "same—same argument" again shows that he was saying the questions comparing '552 Figure 17 to '738 Figures 8, 11, and 12 were the same because Figures, 8, 11, and 12 were the same figures.

Dr. Mullins never said that Figure 17 of the '552 patent was the same as Figure 8 of the '738 patent. (*See also* Mullins Decl. at ¶¶ 4–10.) Gore's anticipation theory is based on a false premise.

2. Figure 17 of the '552 Patent is Visually Different than Figure 8 of the '738 Patent, and No Conclusion Can Be Drawn From Looking at Patent Drawings

A casual examination of Figure 17 of the '552 patent and Figure 8 of the '738 patent suggests that the devices appear different and they would work differently. The waist of Figure 17 of the '552 patent is large in order to entirely fill an atrial septal defect. There is absolutely no evidence in the record that the central portion of Figure 17 would necessarily or even possibly permit lateral movement of the two disks. And, the '552 patent does not hint at a central portion that allows lateral movement. (Carpenter Decl. Ex. 7 at 129:17–22.)

Despite the dissimilarities of the figures, no person of ordinary skill in the art would draw any conclusion about how the central portion of the device shown in the '552 patent operated from a patent figure. Gore's expert, Dr. Gorman, admitted that a person of ordinary skill could not tell how stiff the central portion of a device is by looking at a figure from a patent. (*Id.* at 93:20–95:12.) He testified that one could not determine whether the central portion could bend because the figure reveals nothing about the properties of a device. (*Id.*) Dr. Gorman characterized the patent figures as "cartoons" and explained that patent drawings did not accurately show how device features operated, but rather just showed "an artist['s] interpretation." (*Id.* at 347:24–349:6.) Dr. Gorman's testimony in that regard is consistent with Federal Circuit precedent, namely that "speculative modeling premised on unstated assumptions in prior art patent drawings cannot be the basis for challenging the validity of claims" *Nystrom v. Trex Co.*, 424 F.3d 1136, 1149 (Fed. Cir. 2005); *see also Cacace v. Meyer Mktg. (Macau Commercial*

Offshore) Co., 812 F. Supp. 2d 547, 564–65 (S.D.N.Y. 2011) (applying *Nystrom* to hold that it is inappropriate to rely on prior art patent drawings to show disclosure of claim element where there is no indicia that the patent drawings were to scale, nor language relating to size or angle measurements). Based on this Federal Circuit authority, as well as Dr. Gorman's own testimony, Gore's conclusion based on the size and shape of unscaled, non-dimensioned patent drawings should be rejected.

3. The '552 Patent Specification Does Not Necessitate a Central Portion that Allows Lateral Movement

Gore attempts to construct an argument that a central portion that allows lateral movement is inherent in the '552 patent. Gore's lawyers created a chart of alleged similarities in the description of features in the embodiments of the two patents to argue that the device of Figure 17 of the '552 patent must allow lateral movement because it has characteristics that are similar to characteristics in the '738 patent.

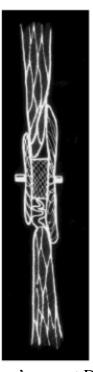
As AGA explained in its summary judgment motion brief, a patent claim cannot be inherently anticipated by a prior art reference unless the missing descriptive matter is *necessarily present* in the prior art:

To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is *necessarily present* in the thing described in the reference. . . . Inherency however, may not be established by probabilities or possibilities. *The mere fact that a certain thing* may *result from a given set of circumstances is not sufficient*.

Cont'l Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1268–69 (Fed. Cir. 1991) (citations omitted) (emphasis added).

a. Gore's Chart Has Meaningless Data

Gore's chart identifies alleged similarities between the two patents that do not inform whether the '552 patent necessarily results in a device that allows lateral movement. (*See* Dkt. 367 at 26–27.) For example, that the '552 device may be used to treat a PFO does not disclose anything. The occluder of the '552 patent had an inflexible central portion that closed a PFO defect in one of two ways. One way was to use the stiff central portion to crush the septum so that the opening in each side of the septum was concentric, as shown below where the bottom of the septum is shown crushed:



(Carpenter Decl. Ex. 8 at pg. 374.) Gore's expert Dr. Javois testified he used the ASO device in this manner. (Carpenter Decl. Ex. 9 at 49:13–50:2) The other way was to manually puncture the septum and use an ASO device straight through. (Carpenter Decl. Ex. 7 at 84:4–86:14.) Neither technique used an occluder with a flexible central portion that allowed lateral movement of the disks, as claimed in the '738 patent.

Similarly, the fact that occluders made according to both patents used 0.005 inch nitinol wire has no bearing on whether the central portion allows lateral movement. (Carpenter Decl. Ex. 5 at 50–54 (stating that size of wires indicates flexibility in general, not that it discloses lateral movement of a central portion); Mullins Decl. Ex. 1 at 19–20).) Nor does the number of wires that are used in the occluder dictate the stiffness of the central portion. (*Id.*) In fact, Gore's own expert refers to these similarities as indicative of flexibility—not lateral movement. (Carpenter Decl. Ex. 5 at 50–54.) Also, the length of the central portion is irrelevant because per the use of the '552 patented device, the central portion went straight through the septum whether the septum was crushed or punctured. Lastly, there is no evidence that the diameter of the relaxed braid before the device is formed and the pick and pitch of wires informs whether the central portion is flexible so that it will allow lateral movement.

Interestingly, Gore's chart does not provide any information about the thickness of the "cylindrical embodiment" or "waist" of a formed device of the '552 patent—that being one factor that **could** relate to the ability to permit lateral movement. (Mullins Decl. Ex. 1 at 17–18.)

b. No Gore Expert has Testified that the Chart Shows that Lateral Movement Is Inherent; Gore Instead Relies Solely on Lawyer Argument

If Dr. Gorman had believed that the '552 patent specification necessarily would result in a device that allowed lateral movement, he would have said so. He did not provide extrinsic evidence that the written specification of the '552 patent establishes that the devices of the '552 patent necessarily allow lateral movement. Dr. Gorman states that

the '552 patent specification "describes how you *could* make the central portion that would allow lateral movement very nicely," not that it is *necessarily* present. (Carpenter Decl. Ex. 7 at 132:7–20 (emphasis added).) Further Dr. Gorman acknowledged that the '552 specification does not disclose that the device **would** allow lateral movement if the device is made in a certain way, and it does not disclose that the central portion should have lateral movement. (*Id.* at 132:18–24.) Dr. Gorman's conclusory opinions about what *could* be done based on the disclosure of the '552 patent are insufficient as a matter of law to create a fact issue for the jury. *Motorola, Inc. v. InterDigital Tech. Corp.*, 121 F.3d 1461, 1473 (Fed. Cir. 1997) ("An expert's conclusory testimony, unsupported by the documentary evidence, cannot supplant the requirement of anticipatory disclosure in the prior art reference itself.") Gore offers only attorney argument about the import of the chart.

c. Dr. Mullins Confirms that the Data in Gore's Chart is Not Relevant to Whether Lateral Movement is Inherent

Dr. Mullins opined that "there is no indication or suggestion to a person of ordinary skill in the art that the tight weave of the wires and the waist geometry of the disclosed ASO device results in a central portion that is flexible to allow the enlarged diameter portions to move laterally." (Carpenter Decl. Ex. 6 at 166:4–10.) Dr. Mullins opined that the "similarities" provided by Gore's attorneys omit a critical element—the width of the "waist" or "cylindrical embodiment." (Mullins Decl. Ex. 1 at 16–20.)

Without that information, and considering the information Gore's attorneys provide about

some similarities between the patent specifications, the '552 patent specification would not necessarily result in a device that would allow lateral movement. (*Id.*)

C. AGA Is Entitled to Summary Judgment of No Anticipation Because No Reasonable Jury Could Find that the '552 Patent Discloses Lateral Movement

No reasonable jury could find that Gore has produced clear and convincing evidence from which the jury could conclude the '552 patent teaches or inherently discloses a central portion that allows lateral movement of the disks.

Instead, AGA's summary judgment motion demonstrates that it is entitled to summary judgment on Gore's anticipation defense based on the '552 patent. (Dkts. 348, 350.) In short, Gore's own expert Dr. Gorman has admitted that the '552 patent does not expressly disclose a device having a central portion. (Dkt. 350 at 7, 9.) Also, AGA's expert agrees that the '552 patent does not disclose or teach the '738 invention. There is no inherency. Thus, under well-settled Federal Circuit authority as well as the lengthy and reasoned *Transclean* decision in this District, which was affirmed by the Federal Circuit (*Transclean Corp. v. Bridgewood Servs.*, 290 F.3d 1364, 1373 (Fed. Cir. 2002)), AGA is entitled to summary judgment. (*Id.* at 14–15.)

Respectfully submitted,

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